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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,647	10/10/2000	Jeffrey M. Friedman	600-1-087CIP/DIV/COM	6790

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David A Jackson Esq
Klauber & Jackson
411 Hackensack Avenue
Hackensack, NJ 07601

EXAMINER

YUCEL, IREM

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/686,647

Applicant(s)

FRIEDMAN ET AL.

Examiner

Yucel Remy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

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DETAILED ACTION

Claims 1-58 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 7, 8 and 12, drawn to a nucleic acid sequence, vector and host cell, classified in class 435, subclass 320.1.
- II. Claims 3-6, 9, 10, 13 and 14, drawn to an isolated nucleic acid encoding an ob polypeptide, classified in class 536, subclass 23.1.
- III. Claims 11, 15, and 16, drawn to probes and primers, classified in class 536, subclass 24.3.
- IV. Claims 17-20, drawn to an ob polypeptide, classified in class 530, subclass 350.
- V. Claims 21, 22, and 28-36 drawn to immunogenic peptide fragments, antibodies classified in class 424, subclass 130.1+.
- VI. Claims 37-48, drawn to methods and kits for screening ob polypeptides, classified in class 435, subclass 7.1.
- VII. Claims 51-55, drawn to methods of reducing body weight and compositions therefor, classified in class 514, subclass 2.
- VIII. Claims 56-58, drawn to methods of increasing body weight and compositions therefor, classified in class 514, subclass 44.

Claims 2 and 23-27 are generic to either group I or II and will be examined to the extent they read on the elected group.

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Claims 49 and 50 are generic to either group VII or VIII and will be examined to the extent they read on the elected group.

This application contains claims directed to patentably distinct species of the claimed inventions (nucleic acids and polypeptides). The nucleotide sequences of claims 1 and 2 (groups I and II) are subject to a restriction requirement. Nucleotide sequences encoding different proteins, probes, primers and nuclear localization sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant's claimed sequences comprise open reading frames that encode different ob polypeptides. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, only one (1) independent and distinct nucleotide or amino sequence will be examined in a single application without restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I-V are drawn to chemically distinct products with distinct functions and modes of operation. For example, the nucleic acids that encode a polypeptide have a distinct and different function from nucleic acids used as primers and probes. Collectively, the nucleic acids

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are different from the polypeptide products and the ob polypeptide possesses different functions and modes of operation than antibodies directed to the ob polypeptides.

The inventions of groups VI-VIII are similarly distinct because the methods of screening for ob polypeptide have a different function (i.e. diagnostic) and effect from the methods of groups VII and VIII, which are drawn to methods of decreasing or increasing body weight.

The products of groups I-III are unrelated to the methods of groups VI, VII and VIII because these methods do not rely upon the nucleic acids of groups I-III.

The products of groups V are unrelated to the methods of group VII because the methods rely upon ob polypeptides, not immunogenic fragments or antibodies. The products of group V is related to the methods of groups VI and VIII as product and method of use; however, because the methods may be carried out using materially different products, the inventions are distinct. For example, methods of increasing body weight may be carried out using anti-sense molecules instead of antibodies (both of which potentially reduce the activity of the ob polypeptide). The methods of screening for polypeptides can be carried out without antibodies; for example by using electrophoresis or northern blot analysis.

Finally, the products of group IV are related to group VII as product and method of use. However, because the product can be used in other processes, such as the generation of antibodies, restriction between the groups is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches required for the different groups are not coextensive, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Remy Yucel, Ph.D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday-Friday, 8:00am-4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.



Remy Yucel, Ph.D.
Primary Examiner
Art Unit 1636

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December 14, 2001